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Applicant: Ahn

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DECLARATION UNDER 37 C.F.R. § 1.132 OF EDWARD S. AHN, PH.D.

I, Edward S. Ahn, Ph.D., hereby declare that:

1. I am one of the co-inventors of the subject matter disclosed and claimed in the subject patent application.

2. My educational background is as follows: I received a Ph.D. in chemical engineering from the Massachusetts Institute of Technology in 2001, and a B.S. degree in chemical engineering from Stanford University in 1994.

3. A particulate tricalcium phosphate (TCP) material having an average particle size of about 5 μm or less, an average crystal size of about 250 nm or less and a surface area of about 20 m^2/g or greater will not necessarily produce an article, upon sintering, having a minimum dimension of about 0.5 cm or greater that further transmits 50% or more of light having a wavelength in the range of about 150 nm to about 1,000 nm.

4. Any number of factors can cause a particulate tricalcium phosphate material satisfying the average particle size, average crystal size, and surface area ranges described above to fail to form an article having a minimum dimension of about 0.5 cm or greater upon sintering. In addition various factors can cause a particulate tricalcium phosphate material satisfying the average particle size, average crystal size, and surface area ranges described above to fail to form an article having a minimum dimension of about 0.5 cm or greater upon sintering that further transmits 50% or more of light having a wavelength in the range of about 150 nm to about 1,000 nm. Such factors can include, among others, the ratio of average crystal size to average particle size, the ratio of average crystal size to surface area, the crystal and/or particle morphology, significant deviations of the calcium to phosphate ratio from 1.50, the degree of crystallinity, the degree of hydration, the presence of hard agglomerates and the presence of chemical impurities or phase impurities.

5. For example, the presence of chemical impurities and/or phase impurities can adversely affect the microstructure of the ceramic preventing particulate TCP from being able to be densified to form upon sintering an article having any substantial minimum dimension and/or prevent the densified article from transmitting light. Possible phase impurities that can be formed during synthesis of tricalcium phosphate include calcium hydrogen phosphate (monetite), octacalcium phosphate, monocalcium phosphate monohydrate, amorphous calcium phosphate, apatitic tricalcium phosphate and hydroxyapatite. Phase impurities can result from the presence of α-TCP in β-TCP, or the presence of β-TCP in α-TCP. Chemical impurities including among other elements and molecules, sodium, potassium, magnesium, carbonates, etc. can hinder densification and/or reduce transparency.

6. In particular, particulate tricalcium phosphate produced via a chemico-mechanical process, such as an attrition mill process as described in Kawamura et al., often contains significant impurities due to the sensitivity of the process to the size and amount of media used for attrition, the size of the container, the speed of the mill, and the like, as well as further impurities derived from the milling media (e.g., metal oxides).

7. I hereby declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like so made are punishable to fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 10/26/09

Edward S. Ahn, Ph.D.